Complete Summary

GUIDELINE TITLE

Malignant melanoma.

BIBLIOGRAPHIC SOURCE(S)

Malignant melanoma. Philadelphia (PA): Intracorp; 2005. Various p. [25 references]

GUIDELINE STATUS

This is the current release of the guideline.

All Intracorp guidelines are reviewed annually and updated as necessary, but no less frequently than every 2 years. This guideline is effective from April 1, 2005 to April 1, 2007.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Malignant melanoma (also called cutaneous melanoma)

- Superficially spreading malignant melanoma
- Nodular malignant melanoma
- Acral lentiginous melanoma
- Lentigo maligna melanoma
- Miscellaneous unusual types

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment
Treatment

CLINICAL SPECIALTY

Dermatology
Family Practice
Internal Medicine
Oncology

INTENDED USERS

Allied Health Personnel
Health Care Providers
Health Plans
Hospitals
Managed Care Organizations
Utilization Management

GUIDELINE OBJECTIVE(S)

To present recommendations for the diagnosis, treatment, and management of malignant melanoma that will assist medical management leaders to make appropriate benefit coverage determinations

TARGET POPULATION

Individuals with malignant melanoma

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation

1. Physical examination and assessment of signs and symptoms
2. Diagnostic tests:
    - Skin lesion biopsy
    - Determination of lesion type, invasiveness, and thickness
    - Chest x-ray (CXR)
    - Lymph node dissection
    - Histological examination from sentinel lymph node (SLN)
    - Reverse transcriptase-polymerase chain reaction assay (RT-PCR)
    - Computerized tomography (CT) scans of head, chest, abdomen

Management/Treatment

1. Regular skin self-examination
2. Complete surgical excision

3. Chemotherapy (dacarbazine) or combined chemotherapy (dacarbazine, carmustine, cisplatin, and tamoxifen)
4. Adjuvant therapy (interleukin [IL-2] and interferon-alpha [IFN-a]); participation in clinical trials; immunotherapies (under investigation)
5. Physical therapy, if indicated
6. Referral to specialists
7. Case management strategies, including case initiation, case management focus, and discharge

MAJOR OUTCOMES CONSIDERED

- Risk factors for malignant melanoma
- Diagnostic and prognostic utility of diagnostic tests
- Effectiveness of treatment interventions

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Searches were performed of the following resources: reviews by independent medical technology assessment vendors (such as the Cochrane Library, HAYES); PubMed; MD Consult; the Centers for Disease Control and Prevention (CDC); the U.S. Food and Drug Administration (FDA); professional society position statements and recommended guidelines; peer reviewed medical and technology publications and journals; medical journals by specialty; National Library of Medicine; Agency for Healthcare Research and Quality; Centers for Medicare and Medicaid Services; and Federal and State Jurisdictional mandates.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

A draft Clinical Resource Tool (CRT or guideline) is prepared by a primary researcher and presented to the Medical Technology Assessment Committee or the Intracorp Guideline Quality Committee, dependent upon guideline product type.

The Medical Technology Assessment Committee is the governing body for the assessment of emerging and evolving technology. This Committee is comprised of a Medical Technology Assessment Medical Director, the Benefit and Coverage Medical Director, CIGNA Pharmacy, physicians from across the enterprise, the Clinical Resource Unit staff, Legal Department, Operations, and Quality. The Intracorp Guideline Quality Committee is similarly staffed by Senior and Associate Disability Medical Directors.

Revisions are suggested and considered. A vote is taken for acceptance or denial of the CRT.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Comparison with Guidelines from Other Groups
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnostic Confirmation

Subjective Findings

- Report of change in size, thickness, or any characteristic of mole(s) or other darkly pigmented growth or spot
    - Partner or family member may be first to observe this if lesion is on individual's back side.
- Itching or bleeding from a skin lesion
- Other primary melanomas may not exhibit these features, therefore are more difficult to recognize

Objective Findings

- The American Academy of Dermatology encourages an "ABCD rule" evaluation for melanoma in any suspiciously pigmented lesion:
    - Asymmetry
    - Border irregularity
    - Color variegation
    - Diameter >0.6 cm
- Changes in surface consistency (ulceration, scaling, etc.)
- Development of raised areas within the lesion or new satellite lesions

Diagnostic Tests

- Skin lesion biopsy
    - Excisional biopsy (must adequately excise the primary tumor), procedure of choice in majority of lesions and usually performed in the physician's office
    - Lesion shaving or curettage is not sufficiently sensitive for diagnosis or staging.
    - Determination of lesion type, invasiveness, and thickness clarifies prognosis and aids in predicting survival rates.
- Chest x-ray (CXR)
    - CXR is performed during the initial assessment to rule out lung metastasis.
- Lymph node dissection
    - Dissection is required when signs of lymph node involvement are present.
    - Histological examination from sentinel lymph node (SLN) biopsy is used to verify melanoma diagnosis.
    - SLN biopsy prediction of disease-free survival is enhanced when combined with reverse transcriptase-polymerase chain reaction assay (RT-PCR measures an RNA-marker that indicates melanoma cells in lymph nodes).
- Computerized tomography (CT) scans: head, chest, abdomen (see Intracorp Imaging guidelines)
    - CT scans are performed to suspected metastatic sites such as bone, central nervous system (CNS), liver, lungs, lymph nodes, and spleen when clinical signs and symptoms of involvement are present (e.g., imaging of the head indicated by headache or seizures)

Differential Diagnosis

- Dysplastic nevi
- Solar lentigo
- Seborrheic keratosis
- Actinic keratosis
- Pigmented basal cell carcinoma
- Vascular lesions (Kaposi's sarcoma, pyogenic granuloma, thrombosed hemangioma)

Treatment Options

- Regular skin self-examination using the ABCD rule (see "Objective Findings" above). Detection and treatment of cutaneous melanoma in its thin, early phase remains the best chance for cure.
    - Care Setting: self-administered
- Complete surgical excision
    - Surgery Care Setting: physician's office, clinic or free-standing outpatient center, acute inpatient facility (for large lesion or if combined with lymph node dissection and/or excision)
- Systemic chemotherapy, mainstay treatment for later-stage disease despite low response rates (see Intracorp Chemotherapy Guideline)
    - Dacarbazine (DTIC), most commonly used single agent; 15 to 25% response rate
    - Combined chemotherapy, agents such as dacarbazine, carmustine, cisplatin, and tamoxifen: best response rates as high as 55%
    - Chemotherapy Care Setting: clinic or free-standing outpatient center, physician's office, or home care: unless severely ill/deconditioned status indicates acute inpatient, subacute/skilled nursing facility inpatient, or hospice admission
- Adjuvant therapy should be offered to patients with high-risk resected disease (nodal metastases or a primary equal or greater than 4 mm).
    - Biologic response modifier therapy, such as interleukin (IL-2) and interferon-alpha (IFN-a), response in small percentage of patients
    - Or participation in clinical trial
    - Care Setting: clinic or free-standing outpatient center, physician's office, or home care
- Immunotherapies, such as cellular vaccines based on cancer-cell molecular biology (DNA) are currently under investigation with hopeful results.

Duration of Medical Treatment

- Complex - Optimal: 28 day(s)
    - This disease could require lifelong treatment.

Additional information regarding primary care visit schedules, referral options, specialty care, physical therapy, and durable medical equipment is provided in the original guideline document.

The original guideline document also provides a list of red flags that may affect disability duration, and return to work goals, including

- Post-excision, small size
- Post-excision, with skin graft

- Post-excision, lymph node dissection
- After recurrent or metastatic disease

Note: Disability may be permanent and the Return to Work is then not applicable.

Case Management Directives (refer to the original guideline for detailed recommendations)

Case Initiation

Establish Case

- Document baseline information, history, key physical findings, patient's understanding, and safety factors.
- See Chemotherapy Chart in the original guideline document.
- The American Joint Committee on Cancer encourages use of the "TNM" classification system (T=primary tumor size; N=lymph node involvement; M=metastasis).
- Provide contact information for local and national support groups.

Coordinate Care

- Advocate for patient by managing utilization and charges.
- Document treatment plan.

Case Management Focus

Activity Deficit

- Document activity alteration as none, mild, moderate, severe, dependent, or bed-bound (based on most recent performance status) and interventions required.

Chemotherapy Intolerance

- Assess status, acute versus chronic, of toxic side effects on rapidly growing tissues, including bone marrow, epithelium, hair, sperm, and document intervention recommended.

Hemodynamic Instability

- Document bleeding complications, severity, and intervention recommended.

Immune Compromised

- Document establishment of protective isolation measures for a white blood cells count (WBC) less than 1,000/mm^3, implying dangerous susceptibly to infection.

Inadequate Nutrition

- Use optimal goal of remaining within 10% of pretreatment weight to document hydration and nutrition deficit as mild, moderate, severe and response needed.

Mental and Emotional Alteration

- Ensure accurate diagnosis of any change in mental status.
- Document baseline or optimal mental and emotional functioning and their alterations due to cancer presence, comorbidity, surgery, or treatments.
- Assess and respond appropriately to the degree of debility caused by alterations listed in the original guideline document through benefit coordination or community resource activation.

Pain Control

- Assess pain severity associated with excision of melanoma lesion(s) and extent of any resultant activity deficits and need for physical therapy (PT) or nursing interventions.
- Document optimal pain management by characterizing severity and interventions undertaken to remedy or manage pain.

Oncologic Emergencies

- Immediately report to the physician or activate emergency medical technician (EMT) system as necessary for skin graft disruption or skin flap necrosis, signs and symptoms of CNS infection (common, major problem), ulceration of lesions.
- Document presence of or developing oncologic emergencies and report to attending physician, surgeon, or activate EMT system as necessary.

Radiation Intolerance

- Document presence and severity of radiation side effects.
- Initiate early interventions for complications of radiation therapy.

Respiratory Instability

- Document respiratory deficit as mild, moderate, severe, and dependent, and respiratory rehabilitation enhancement measures.

Skin Integrity Deficit

- Document type (split-, full-thickness, or flap), dimensions, and location of skin graft(s) necessary for wide excisional surgeries.
- Assess periodically the condition of any extremity receiving high concentration chemotherapy by regional perfusion (with or without concomitant potentiating hyperthermia) for required nursing interventions.
- Document severity of skin integrity disruption.

Terminal Care

- Document optimal comfort measures and palliative care initiatives.

Discharge

Discharge from Case Management (CM)

- Document return to independence or stabilized functional status and closing conversations with patient, caregiver, physician, pharmacist, and care providers.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Potential Benefits

Appropriate diagnosis, treatment, and management of malignant melanoma that assist medical management leaders to make appropriate benefit coverage determinations

Specific Potential Benefits

- Skin lesion biopsy: Determination of lesion type, invasiveness, and thickness clarifies prognosis and aids in predicting survival rates
- Lymph node dissection: Sentinel lymph node (SLN) biopsy prediction of disease-free survival is enhanced when combined with reverse transcriptase-polymerase chain reaction assay
- Systemic chemotherapy: Dacarbazine (DTIC) has a 15 to 25% response rate; Combined chemotherapy, agents such as dacarbazine, carmustine, cisplatin, and tamoxifen have best response rates as high as 55%
- Detection and treatment of cutaneous melanoma in its thin, early phase remains the best chance for cure.

POTENTIAL HARMS

Refer to the Case Management Focus section of the "Major Recommendations" field for information on potential complications and strategies to address them, or refer to the original guideline document.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Malignant melanoma. Philadelphia (PA): Intracorp; 2005. Various p. [25 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1997 (revised 2005)

GUIDELINE DEVELOPER(S)

Intracorp - Public For Profit Organization

SOURCE(S) OF FUNDING

Intracorp

GUIDELINE COMMITTEE

CIGNA Clinical Resources Unit (CRU)
Intracorp Disability Clinical Advisory Team (DCAT)
Medical Technology Assessment Committee (MTAC)
Intracorp Guideline Quality Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Intracorp guidelines are available for a licensing fee via a password protected, secure Web site at www.intracorp.com.

Reprints of complete guideline content may be purchased for $35.00 per title (plus tax in TX at 8.25% and CT at 1.0%). Please send e-mail request to lbowman@mail.intracorp.com.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Policies and procedures. Medical Technology Assessment Committee Review Process. Philadelphia (PA): Intracorp; 2004. 4 p.
- Online guideline user trial. Register for Claims Toolbox access at www.intracorp.com.

Licensing information and pricing: Available from Intracorp, 1601 Chestnut Street, TL-09C, Philadelphia, PA 19192; e-mail: lbowman@mail.intracorp.com.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on May 25, 2005. The information was verified by the guideline developer on June 7, 2005.

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